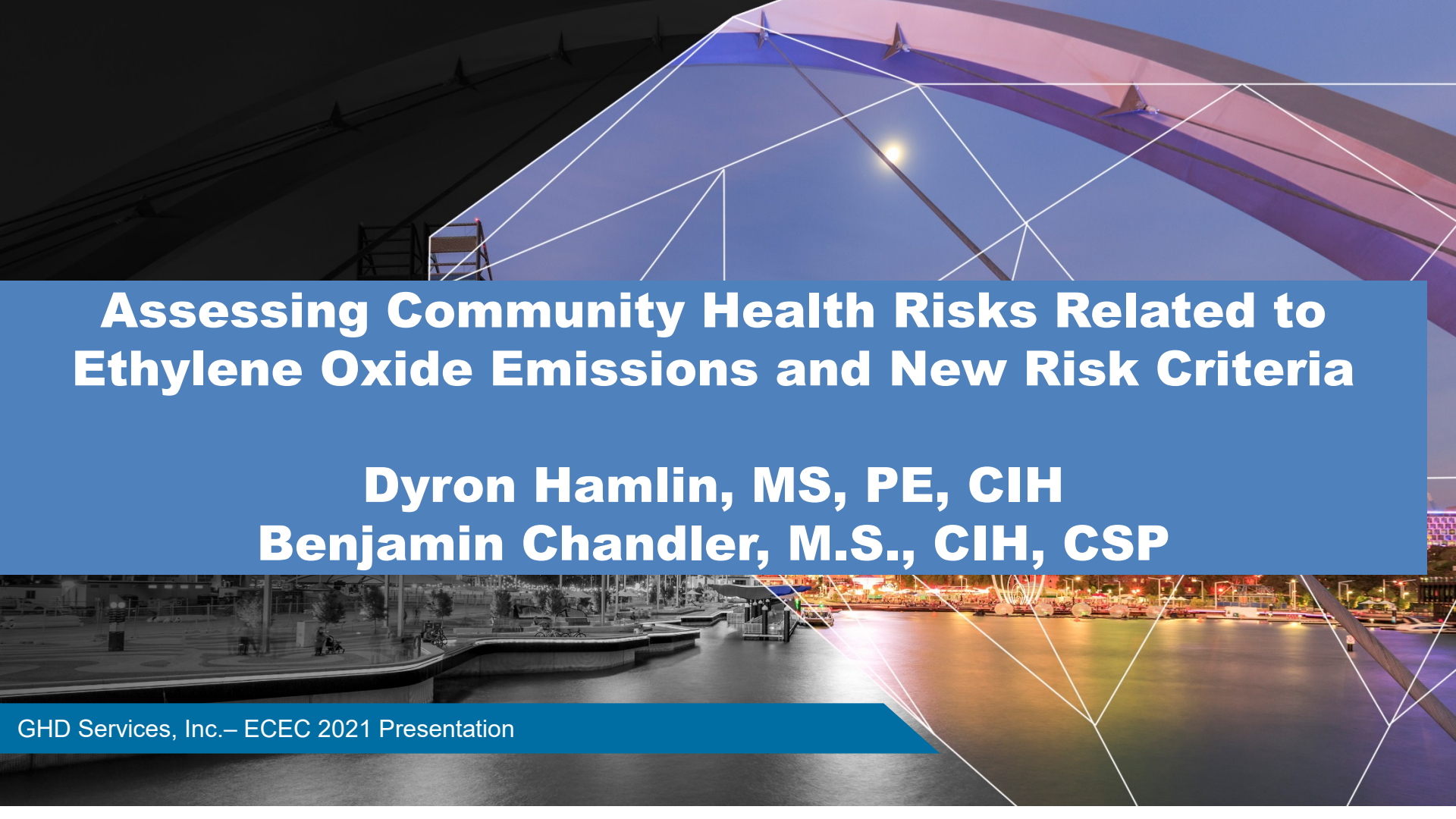

Assessing Community Health Risks Related to Ethylene Oxide Emissions and New Risk Criteria

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GHD Services, Inc.– ECEC 2021 Presentation

Ethylene Oxide Uses

- Commonly used in the chemical industry as an intermediate compound
- Manufacturing process for fiberglass
- Sterilization of medical equipment and pharmaceutical products
- Ingredient in industrial cleaners
- Produce ethylene glycols for engine antifreeze
- Personal care products – cosmetics and shampoos

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Ethylene Oxide – Health Risks

- Known Human Carcinogen – NTP
- Group 1 Carcinogen – IARC
- Potential Human Carcinogen – NIOSH
- Suspected Human Cacinogen (A2) – ACGIH
- Cancer / Reproductive Hazard – OSHA
- Increase cancers of white blood cells, including non-Hodgkin's lymphoma, myeloma, and lymphocytic leukemia
- Skin Irritant
- Target Organs – Central Nervous System

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Ethylene Oxide Properties

- Extremely flammable liquid and gas under pressure
- Highly reactive
- Flammable Range = 2.6% - 100%
- Clear colorless gas
- Sweet odor reported in industrial settings
  - Reminiscent of bruised apples

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Ethylene Oxide – Occupational Exposures

- Primary Routes of Exposure
  - Inhalation
  - Eye contact
  - Skin contact/absorption
- Occupational Exposure Limits
  - OSHA PEL-TWA = 1 ppm
  - OSHA PEL-STEL = 5 ppm
  - ACGIH TLV-TWA = 1 ppm
  - NIOSH IDLH = 800 ppm
- No real-time personal air monitoring instrument

Ethylene Oxide – Workplace Compliance

- OSHA Substance Specific Standard – 29 CFR 1910.1047
  - General Industry
  - Worker Monitoring
  - Regulated Areas
  - Respiratory Protection and Controls
  - Written Program
  - Medical Surveillance
  - Notification and Training
  - Recordkeeping

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Occupational Safety and Health Administration

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Ethylene Oxide – Worker Protection

- NIOSH Respirator Recommendations (Up to 5 ppm)
  - Full face Air Purifying Respirator – APF=50
  - Escape and Workplace
  - SCBA – APF = 10,000 / Emergency
- Some manufacturers recommend Supplied Air
  - Poor warning properties
  - High odor threshold
- Respiratory Protection Program

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Ethylene Oxide – Environmental Protection

- EPA Listed Hazardous Air Pollutant
- Process Safety Management
  - Threshold quantity 5,000 lbs
  - 29 CFR 1910.119
- EPA Clean Air Act
- National Air Toxics Assessment
  - 2014 Air Data
  - EPA is evaluating emission levels and workplace controls
- Facility Air Permitting

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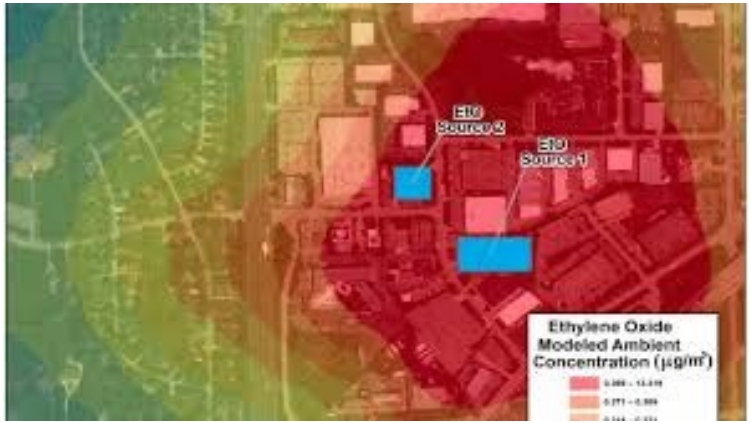
Ethylene Oxide Impacts – How We Got Here

- Sterigenics – Medical Equipment Sterilization using EtO / Willowbrook, Illinois
- EPA Lowers Health Criteria for Cancer Risk Based on IRIS Assessment – 2016
- ATSDR Report Indicates Increased Cancer Risks for Willowbrook Residents – 2018
  - Modeled Data
  - 30 Day Sampling Study
- Community Uncertainty and Concerns
- Multiple Ongoing Lawsuits



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Ethylene Oxide – What are the Risks?

- Task Force of Experts Convened
  - Certified Industrial Hygienist
  - Toxicologist
  - Chemical Engineer
- Air Sampling Study was Implemented
- Ultimately Resulted in Seal Order
- Sterigenics Implemented Additional Control Measures
- Pending Litigation and Continued Air Sampling and New Legislation Introduced
- National Attention on the Sterilization Services Industry

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Strategies for Assessing Health Risks

TASK FORCE OBJECTIVES

- Identify Laboratory Methods and Implement Air Sampling Protocols
- Quantify EtO Concentrations at Indoor and Outdoor Locations (Rep. Air Samples)
- Identify Sources of EtO and Evaluate the Potential Contributions
- Measure Background Concentrations of EtO in Urban and Rural Areas
- Provide Guidance on Health Risk

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What is Being Done to Understand Risks

- Active Role by local Municipalities and State / County Government
- County Health Departments
- Industry Trade Associations
- Advocacy Groups
- Users / Manufacturers of EtO – Proactive Sampling
  - Medical Sterilization
  - Chemical Industry
  - Transportation
- Implementing Additional Controls Measures to Reduce EtO Emissions

Example Community Activist Messaging

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Strategies for Determining Health Risk

HEALTH RISK CRITERIA (1:10,000 / 1:1 million)

- EPA – 0.01 ppb / 0.0001 ppb
- ACC –24.5 ppb / 0.245 ppb
- TCEQ – 40 ppb / 0.4 ppb

AIR SAMPLING METHODOLOGIES

- Evacuated SUMMA Canister
- 24 Hour Regulator / 6 Liter
- EPA Method TO-15 (GC/MS)
- Multiple Laboratories
- Detection Limits Vary by Laboratory ~ 0.02 ppb
- Potential Interferences - Trans-2-Butene, Acetaldehyde

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Air Sampling Data Results and Interpretation

COLLECT QUALITY / INDEPENDENT DATA TO CHARACTERIZE AIRBORNE ETO CONCENTRATIONS IN THE COMMUNITY

- 200+ Ambient Air Samples
- Sample Period – November 2018 through August 2019
- Indoors vs Outdoors Concentrations
- Upwind and Downwind Sample Locations
- Collocated with EPA / Sterigenics Consultant
- Facility Operating vs Shutdown
- Consistently Measured Background EtO above the EPA Risk Criteria
- Positive Detections Noted Indoors and Outdoors
- Other Sources are Contributors

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National Emphasis – Qualifying the Risk beyond Willowbrook

- Multiple Air Sampling Projects
  - Sterilization Companies
  - Chemical Producers
  - Local Municipalities
  - Health Departments
  - Trade Organizations
- > 1,000 ambient air samples
- Throughout the US
- Different Laboratories
- Qualifying ambient concentrations compared to wind direction

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Unique Challenges for Public Health Experts

- Comparison of Air Sampling Data to Long-term exposure risk criteria
- Limited Amount of Ambient Air Data
- Lack of Understanding on Potential Sources
- Absence of Measured Background Concentrations
- Few Studies on EtO in the Community
- Validation of the Laboratory Method
  - MDL is above EPA Risk Criteria
  - Identified Interferences and Limitations
  - No identified Real-Time Instruments
- Emissions Control Measures in Compliance
- What is the Safe Level of EtO?

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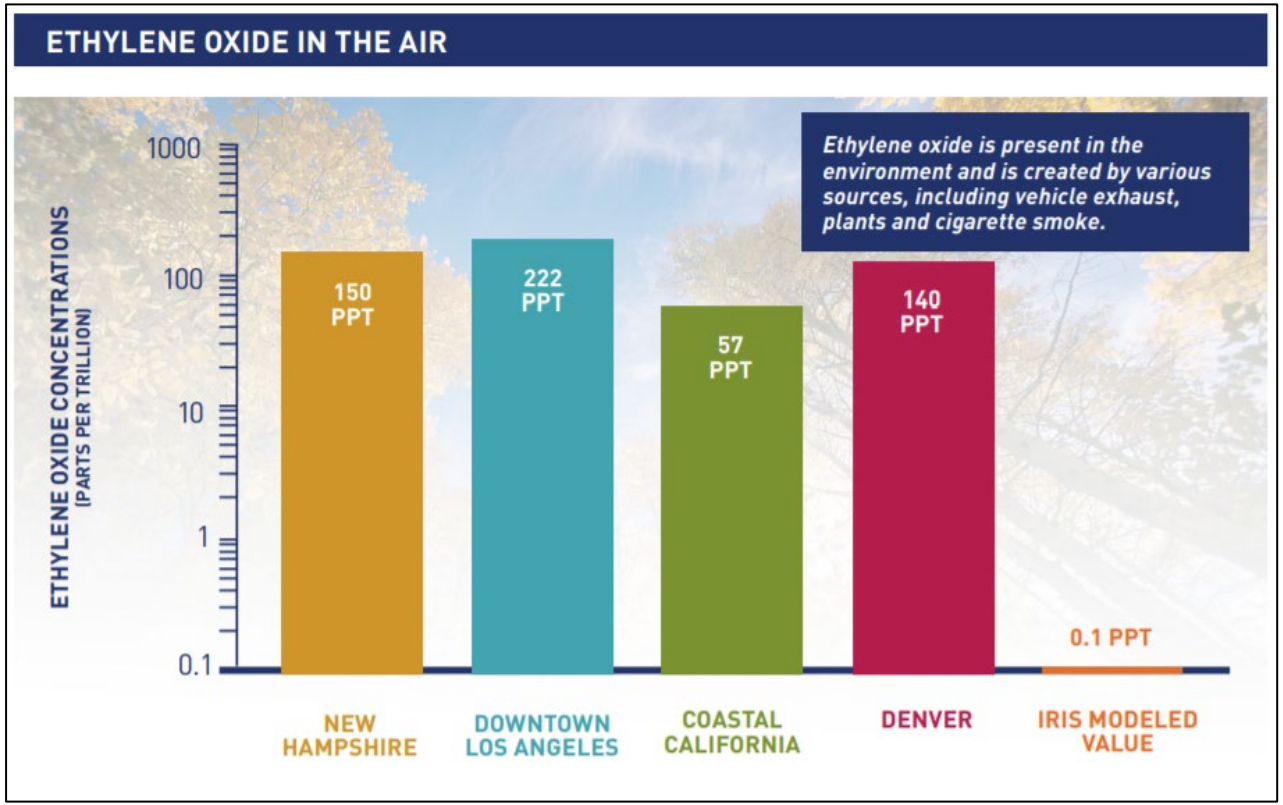
Ethylene Oxide in the Environment



Source: https://www.americanchemistry.com/eo/Ethylene-Oxide-Safety-Facts.pdf

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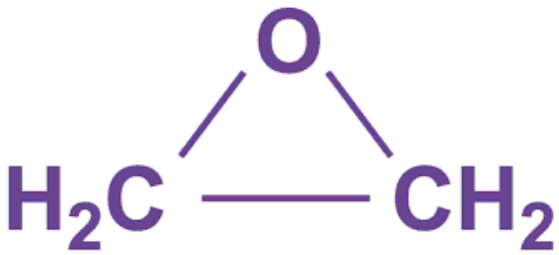
What's Next with Ethylene Oxide

- Multiple Medical Sterilization Facilities have discontinued operations
  - Implementing control measures
  - Directed by Regulators
  - Pressure from Public / Business Decisions
- Continued Debate Regarding Health Risks / Appropriate Risk Values
- New Monitoring Technologies
- Further Studies on Sources, Ambient Levels / Indoor



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Questions?

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